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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,185	01/20/2004	Austin W. Mutchler	DEP5031	2594

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT PAPER NUMBER

3733

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,185

Applicant(s)

MUTCHLER, AUSTIN W.

Examiner

Jerry Cumberledge

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10-16, 18-27, 29, and 31, as best understood by the examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by Border (US Pat. 5,935,127).

Border discloses an intramedullary nail for use with a first fastener and a second fastener for use in orthopedic surgery, said nail comprising a body (Fig. 1, 10) defining a longitudinal axis thereof, the body defining an aperture (Fig. 1, 16) therethrough, the aperture having a first portion (Fig. 1, 17) capable of cooperation with a first fastener to provide dynamic fixation and having a second portion (Fig. 1, 22) capable of cooperation with a second fastener to provide static fixation. The definition of axis, according to the Merriam-Webster Online Dictionary, is “a straight line about which a body or a geometric figure rotates or may be supposed to rotate.” Since the nail can rotate in any direction around any line or point where the nail exists in space, the axes can be anywhere in the body of the nail, in any orientation. This definition of axis will be applied throughout this office action. The “portions” can be considered part of the slot since they are continuous with the slot.

The slot (Fig. 1, 16) has a rectangular central section. As seen in Fig 1, the cross section of the middle of the slot has a rectangular section. It also has a cylindrical end

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section (Fig. 1, 26) adjoining the rectangular central section. The cylindrical end section is capable of matingly fitting with the first fastener. The cylindrical end section is capable of slidable fit and threadable fit with the first fastener. The definition of thread, according to the Merriam-Webster Online Dictionary, is "to pass something through in the manner of a thread". The end is capable of threadable fit with the first fastener, since the screw could be placed through the end section. The aperture is capable of providing for a slidable fit of the first fastener with the body along the longitudinal axis of the body. If the diameter of the fastener's body is smaller than the diameter of the aperture, there would be room enough for the screw to slide in the aperture. The slot further includes a second cylindrical end section (Fig. 1, 22) opposed to the first mentioned cylindrical end section. The nail includes a resorbable component (Fig. 1, 19) for cooperation with said body adjacent the aperture. The resorbable component comprises external threads formed thereon (column 4, lines 31-35). The slot defines a slot axis thereof, the slot axis being perpendicular to the longitudinal axis of said body.

Border further discloses a kit for use in orthopedic surgery, the kit comprising: a first fastener (Fig. 3, 34); a second fastener (Fig. 3, 34); and an intramedullary nail comprising a body (Fig. 1, 10) defining a longitudinal axis thereof, the body defining an aperture therethrough (Fig 1, 16), the aperture having a first portion (Fig 1, 17) capable of cooperation with said first fastener to provide dynamic fixation and having a second portion capable of cooperation with said second fastener to provide static fixation (Fig. 1, 22). The slot has a rectangular central section. As seen in Fig 1, the cross section of the middle of the slot has a rectangular section. It also has a cylindrical end section

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(Fig. 1, 26), which is attached to the rectangular section. The cylindrical end section is capable of matingly fitting with the first fastener. The cylindrical end section is capable of slidable fit and threadable fit with the first fastener. The aperture is capable of providing for a slidable fit of the first fastener with said body along the longitudinal axis of said body. The slot further includes a second cylindrical end section (Fig. 1, 22) opposed to the first mentioned cylindrical end section. The kit comprises a resorbable component (Fig. 1,19) capable of cooperation with said body adjacent the aperture. The resorbable component comprises external threads formed thereon (column 4, lines 31-35) for cooperation with the internal threads of said body. The slot defines a slot axis thereof, the slot axis being perpendicular to the longitudinal axis of said body.

The intramedullary nail of Border is capable of performing a method for use in orthopaedic surgery comprising: providing an orthopaedic surgery kit including a first fastener, a second fastener, and an intramedullary nail having a body defining longitudinal axis thereof, body defining an aperture therethrough, the aperture having a first portion for cooperation with the first fastener to provide dynamic fixation and having a second portion for cooperation with the second fastener to provide static fixation; cutting an incision in the patient; preparing a bone cavity; inserting the nail into the cavity; choosing one of static fixation and dynamic fixation for the surgery; selecting one first fastener and second fastener based on the choice of one of static fixation and dynamic fixation the surgery; and securing the chosen one of the first fastener and the second fastener into the nail.

Border further discloses an intramedullary nail for use in orthopaedic surgery, said nail comprising: a body (Fig. 1, 10) defining a longitudinal axis and a transverse axis thereof, the transverse axis being normal the longitudinal axis, the body defining an aperture (Fig. 1, 16) therethrough, the aperture being substantially longer in the longitudinal axis than in transverse axis. The aperture is longer in some directions than others, and, applying the definition of axis, the axis can exist anywhere the nail is and in any direction. The aperture defines an enlarged portion (Fig. 1, 17) thereof along the longitudinal axis. Enlarge is defined by the Merriam-Webster Online Dictionary as "extend." It is longer in one direction than the other (Fig. 1, 17), hence it is extended in one direction and enlarged. The aperture has a rectangular central section. As seen in Fig. 1, the cross section of the middle of the slot has a rectangular section. The enlarged portion forms a generally cylindrical section and is positioned adjacent an end of the aperture. Viewing the enlarged portions from above the nail, as in Fig. 1 and Fig. 5, they have a generally cylindrical shape. Border discloses a fastener (Fig. 3, 34) capable of cooperation with the body. The cylindrical section of said body is capable of matingly fitting with said fastener. The cylindrical section is capable of slidable and threadable fit with said fastener. The aperture is capable of a slidable fit with the fastener with said body, along the longitudinal axis of said body. The aperture further includes a second enlarged cylindrical section (Fig. 1, 22) opposed to the first mentioned cylindrical section. Border discloses a resorbable component capable of cooperation with said body adjacent the aperture (Fig. 1, 19). The resorbable component comprises external threads formed thereon (column 4, lines 31-35). The enlarged

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portion is adjacent an end of the aperture. According to the Merriam-Webster Online Dictionary, the definition of adjacent is "not distant". The enlarged portion is only a few inches from the end of the aperture, which is not distant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 9, 17, 28 and 30, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Border in view of Emilio et al (US Pat. 5,814,047).

Border discloses the claimed invention except for the body adjacent the first mentioned cylindrical end defining internal threads therein and the body adjacent the second cylindrical end defining internal threads therein.

Emilio et al. disclose the body adjacent the first mentioned cylindrical end (Fig. 12 below, 130) defining internal threads therein (Fig. 12, 131) and the body adjacent the second cylindrical end (Fig. 12, 140) defining internal threads therein (Fig. 12, 141) (see also Fig. 9 below), for engagement and guiding of screws (Column 5, lines 19-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to construct the body adjacent the aperture of Border with the

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internal threads of Emilio et al., in order for the internal threads to engage and guide screws used to fasten the nail to the bone (Column 5, lines 19-24).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Border in view of Emilio, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Response to Arguments

Applicant's arguments filed 09/28/2006 have been fully considered but they are not persuasive.

In response to the applicant's argument that the Border reference does not disclose an aperture that has a portion that can be used with a fastener to create static fixation, the examiner respectfully disagrees. The aperture of Border (Fig. 1, 16) is the longitudinal bore that extends through the nail from end to end (column 2, lines 33-35). Slot 17 and bores 22 are continuous with the aperture 16, as shown in Fig. 3. Thus, the

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slot 17 and bores 22 can be considered to be part of aperture 16. The slot 17 can be considered to be the first portion of aperture 16, and bores 22 can be considered to be the second portion of the aperture. The first portion (slot 17) can contain resorbable material through which a fastener such as a bone screw can be placed (column 3, lines 38-49), which can be used in dynamic fixation (column 3, lines 49-52). The second portion (bores 22) do not include the resorbable material, and could be used to statically fix two bone fragments. One fastener could be placed through one bore 22 into one bone fragment and another fastener could be placed through the second bore 22 into a second bone fragment.

Furthermore, with regards to intended use and other functional statements (e.g. ... for cooperation with the first fastener to provide dynamic fixation ...for cooperation with the second fastener to provide static fixation...), they do not impose any structural limitations on the claims distinguishable over the device of Border, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion



The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER

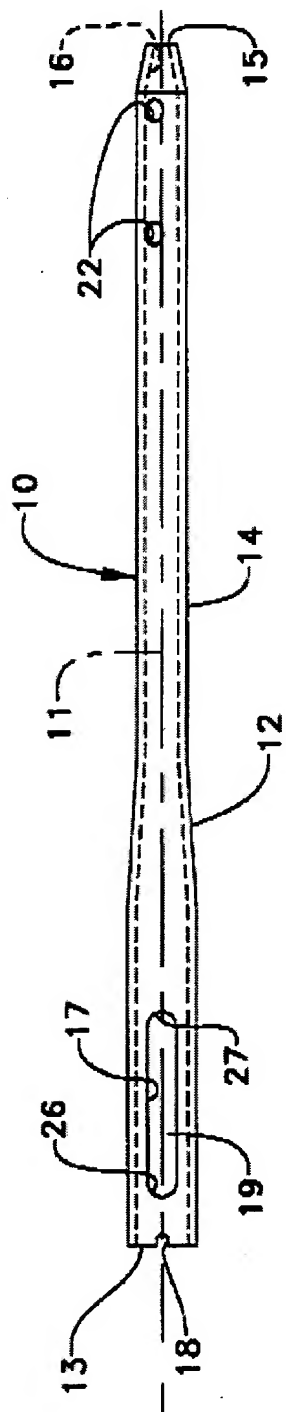


FIG. 1

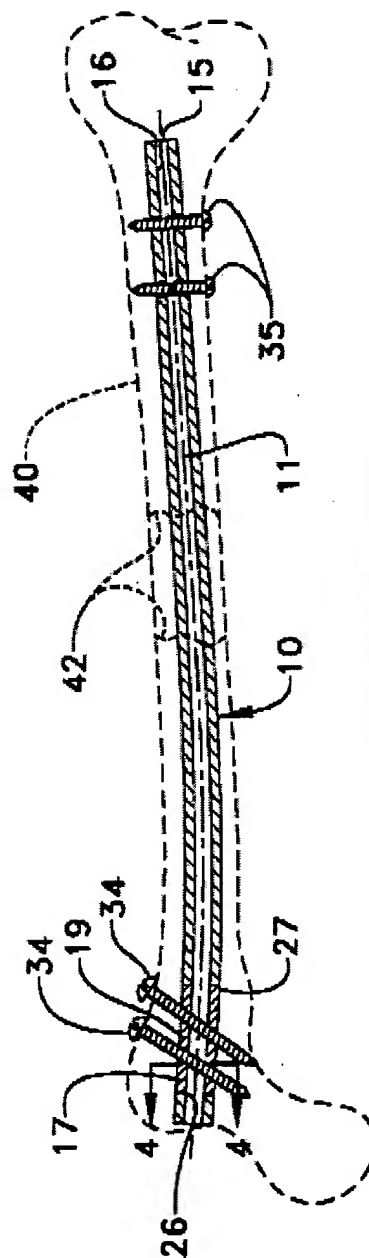


FIG. 3

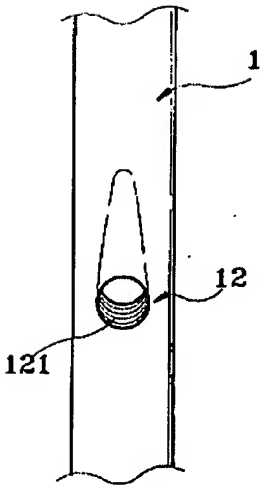


Fig. 9

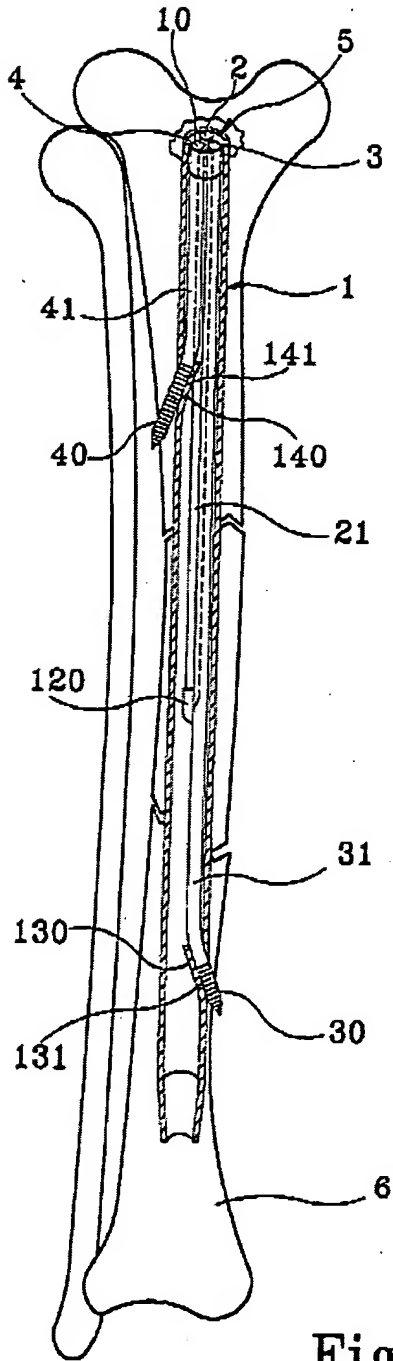


Fig. 12